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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,373	12/27/2001	Hideji Tajima	10287.48	5376

27683 7590 11/03/2004

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,373

Applicant(s)

TAJIMA ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24, 29 and 30 is/are allowed.
- 6) ☒ Claim(s) 22, 23, 25-28 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on August 03, 2004 has been acknowledged and entered.

Claims 22-31 are pending.

Withdrawn Rejection(s)

Rejection under 112, 2nd paragraph in the previous office action is withdrawn hererin.

Newgrounds of Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22, line 4, "capable of" is indefinite because it is unclear of what is being modified for the carriers to be capable of holding micro-substances and the remote-acting bodies. See also claims 24 and 25 for the same problem. See also claim 27 for "capable of" holding the micro-substances and the remote-acting bodies.

Claim 22, line 9, "the suspension system" lacks antecedent support. The relationship of the "carriers" to the "remote-acting bodies" and the "microsubstances" is unclear. Lines 8-9 are unclear as to how the remote-acting bodies and microsubstances are held to the carrier by agitation. Agitation should remove anything attached to the

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carrier since there is no means recited on the carrier that can hold the remote-acting bodies and the microsubstances.

Claim 24, line 13, is unclear of whether the "sterilized reductive enzyme" is poured alone by itself or in addition to the remote-acting bodies, the micro-substances and the carriers.

Claim 24, line 8, "the suspension system" lacks antecedent support. Lines 7-8 are not clear of how the carrier does the "holding" with agitation. (see explanation in rejection of claim 22). Claim 24 is also unclear of how a gas or solid be a "liquid culture medium" in lines 15-16.

Claim 25, line 9, "the suspension system" lacks antecedent support. In lines 8-9, it is unclear of how the carrier does the holding with agitation. (see explanation in rejection of claim 22).

Claim 29, "the micro-organisms" lacks antecedent support.

Maintained Rejection(s)

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 23, 25-28, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Forrest et al. (US 4,659,678).

Forrest et al. teach a method of immunoassay of an antigen in a liquid sample comprising mixing the antigen (micro-substance), magnetic cellulose particles (remote-acting bodies and carriers) bound to antibodies to the antigen known as the antibody reagent; the mixture is incubated for a certain amount of time; a magnetic field (remote force) is applied to separate the bound from unbound. The antibody reagent comprises of anti-FITC polyclonal antibody covalently coupled with magnetizable cellulose particles which are composites of cellulose containing black ferric(ous) oxide (Fe_3O_4). Magnetic field can be used to manipulate or separate the antigen-bound antibody-magnetizable cellulose particles from the unbound antibody-magnetizable particles. (See col. 3, lines 30-56; col. 8, lines 15-40). The magnetic particles of Forrest are equivalent to the carrier and the remote-acting bodies of the claimed invention. Since the claimed invention fails to exclude that the carriers and the remote-acting bodies are separate entities, the magnetic cellulose particles which are composite of cellulose containing black ferric(ous) oxide (Fe_3O_4) read on the claimed carrier and remote-acting bodies. The target analytes can be proteins, immunoglobulins, which include antibodies. Antibiotics include antibodies. (see abstract). Prior to pouring, the carriers, the remote-acting bodies and the micro-substances are separately prepared. To start out the preparation of the magnetizable cellulose particle, the cellulose and the magnetic particles have to be prepared separately before they are mixed. Since Forrest teaches mixing the suspension after incubation, agitation must have taken place. The specification of the present invention describes that the carriers that have a plurality of holes, cavities, concavities, or convexities are made up of cellulose and Forrest teaches

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that magnetic particles comprises cellulose and magnetite, the cellulose in Forrest must have a plurality of holes, cavities, concavities or convexities because these carriers are made up of the same material. In Forrest, since the magnetite or remote-acting bodies are fixed to the holes, cavities, etc. of the cellulose, and the antigen/micro-substance is fixed to the magnetic particles, the antigen/micro-substance must be fixed to the holes, cavities etc. of the carrier or cellulose as well. Thus, the requirements of claims 27 and 28 are satisfied.

Response to Arguments

Applicant's arguments filed on August 03, 2004 have been fully considered but they are not persuasive.

Applicants submit that Forrest US Patent No. 4,659,678 fails to teach: "pouring remote-acting bodies which can be positionally manipulated by a remote force, micro-substance including a target substance of an assay, and carriers capable of holding the micro-substances and the remote-acting bodies, into a liquid, a gas or a solid in accordance with a predetermined order, making the remote-acting bodies and the micro-substances be held in the surfaces of the carrier by agitating the suspension system..."

Forrest teaches incubating magnetic cellulose particles that are equivalent to remote-acting bodies and carriers, bound to antibodies to the antigen (target substance of an assay) for 5 minutes before mixing. (see col. 9, lines 40-50). The remote-acting bodies and carriers are magnetic cellulose particles. The specification of the present invention describes on page 9, lines 10-13, that the carrier can be cellulose and the

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remote-acting bodies can be magnetic particles. Thus, a magnetizable cellulose particle can satisfy the requirement of the remote-acting bodies attached to the surface of the carrier. Since the micro-substance is attached to the magnetizable cellulose particle, it must be attached to the surface of the carrier as well. Forrest teaches that after incubating the mixture of the magnetizable cellulose particle and the antigen, the suspension is mixed. According to the specification the device to agitate the mixture is a "mixer", see page 25, lines 10-11. Thus, if Forrest teaches mixing the suspension, then a mixer must be used. Thus, agitation must have occurred.

Allowable Subject Matter

Claims 24, 29, 30 are allowed.

Conclusion

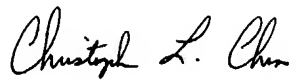
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
October 22, 2004


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641
11/1/04